



**IMPACT OF SHORT COUNSELLING SESSIONS ON QUALITY OF LIFE OF ASTHMA  
AND COPD PATIENTS IN A TERTIARY CARE HOSPITAL: A PROSPECTIVE  
RANDOMISED CONTROLLED STUDY**

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**ABSTRACT**

**Background & Objectives:** The burden of Asthma and COPD in India is huge. Patient education in this demographic has proven to be effective in improving the quality of life and in reducing the number of exacerbations requiring hospitalisation. This study aims at assessing the effectiveness of short counselling sessions, designed keeping in mind the high number patients in Indian Healthcare Settings, on the quality of life of such patients. **Methods:** A total of 102 subjects were included in this study and randomly allocated to either the Intervention Group (n=51), to whom counselling was given, or to the Usual Care Group (n=51), to whom counselling was not given. These subjects were followed for 1 month and outcomes were measured in terms of changes in HRQoL using the SGRQ, changes in medication adherence using the MAQ, changes in technique to use inhaler, and number of exacerbations requiring hospitalisation. **Results:** Clinically and statistically significant improvement of HRQoL was seen in Intervention Group over Usual Care Group. There was a difference of 11.44 points (P=0.002) on the SGRQ between these two groups. At the end of 1 month, the proportion of lowly adherent subjects was 2% in the Intervention Group, while that of the Usual Care Group was 30% (P<0.001). **Interpretation and Conclusions:** Short counselling sessions proved effective in improving quality of life. Due to their feasibility in Indian healthcare settings, if adopted, such short counselling sessions can be an instrumental part of intensive management strategies for Asthma and COPD patients.

**KEYWORDS:** Asthma, COPD, Counselling, Patient Education, Quality of Life, Short Counselling Session.

**INTRODUCTION**

In India there are about 17.23 million cases of Asthma and about 14.84 million cases of Chronic Bronchitis.<sup>[1]</sup> About 500,000 deaths occur in India annually due to COPD.<sup>[2]</sup> COPD is the leading cause of deaths in Maharashtra State. Deaths on account of COPD surpass that of coronary artery disease, cerebrovascular accidents and diabetes combined.<sup>[3]</sup> In the year 2011, the estimated economic loss in India due to COPD was about INR 35,000 crores, which was more than the Ministry of Health and Family Welfare's annual budget of INR 25,124 crores for the year 2010-2011.<sup>[2,4]</sup> A study that assessed costs of treatment among 423 COPD patients in India found that patients spend about 30% of their annual income on management of the disease.<sup>[5]</sup> It has been estimated that guideline-based management of COPD can bring these costs down by approximately 70%.<sup>[4]</sup> In the year 2015, the financial burden on India for treating Asthma was estimated to be about INR 13,945 crores, excluding any indirect cost incurred due to Asthma. This

cost can most likely be brought down to about INR 4,850 crores if all Asthmatics were to be treated in accordance with evidence-based guidelines.<sup>[6]</sup>

These facts highlight the urgent need for additional strategies to further intensify the management of these diseases. Counselling seems a feasible and viable option in context of Indian Healthcare scenario. Counselling sessions usually last for more than 2-3 hours. Such lengthy sessions are highly impractical in the context of Indian healthcare settings. Therefore, we designed and conducted this study to evaluate the impact of short counselling sessions, lasting no longer than 20 minutes.

**METHODS AND MATERIALS**

**Objectives**

The primary objectives of this study were to understand the impact of counselling provided to COPD and Asthma patients in terms of changes in:

- Health Related Quality of Life (HRQoL) measured using St. George's Respiratory Questionnaire (SGRQ).
- Patient's medication taking behaviour measured using Medication Adherence Questionnaire (MAQ).
- Patient's ability to correctly use inhalational pumps measured using Inhaler Technique Assessment Form.
- Number of exacerbations and unscheduled hospital visits in a month.
- FEV<sub>1</sub> and FEV<sub>1</sub>:FVC values measured using MIR SPIROLAB III®.

### Study Design and Population

This was a single centre, longitudinal, prospective, randomized, controlled study. The study was given ethical approval by the Institutional Ethics Committee (IEC) of Government Medical College, Aurangabad (Pharma/IEC-GMCA/515/2017) dated 23/10/2017. The study started in November 2017 and continued until March 2018. Participants enrolled into the study included patients admitted to the male and female wards of the Medicine Department of the Government Medical College and Hospital, Aurangabad.

### Inclusion Criteria

- Must be diagnosed with COPD (as per GOLD guidelines) OR with Asthma (as per NHLBI guidelines for diagnosis and management of asthma).
- Must be between the ages of 13 years to 85 years at the time of enrolment.

### Study Procedure

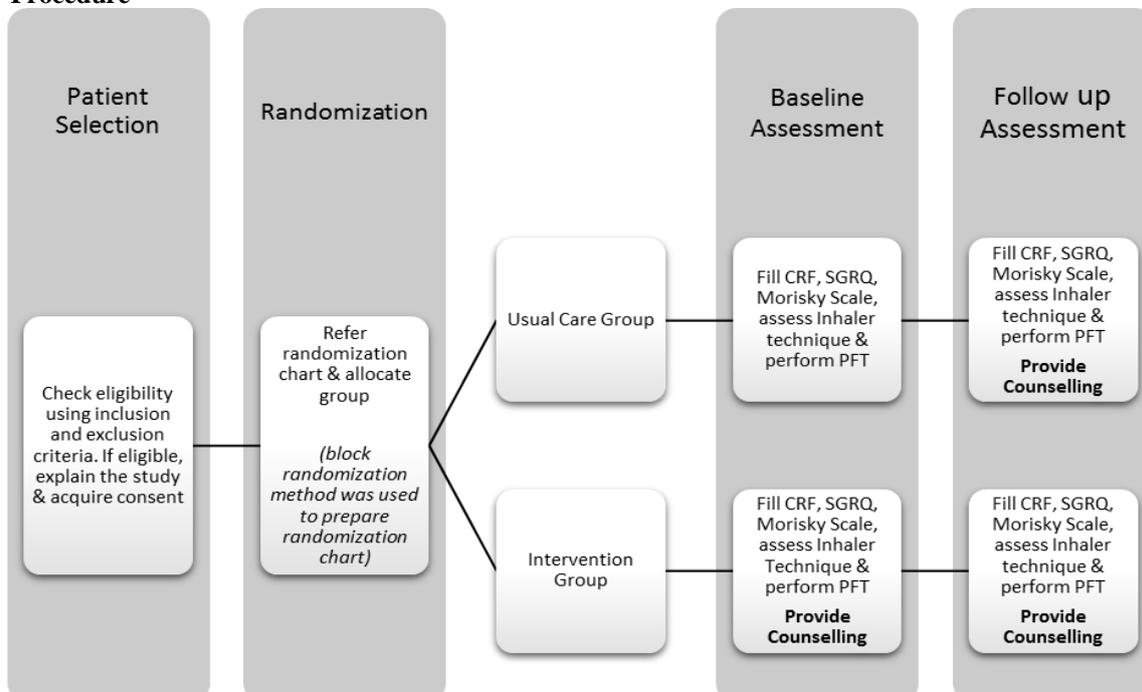


Figure. 1: Study procedure.

**Baseline Visit:** Once a patient was allocated to a particular group, he was given the SGRQ and the MAQ (also known as the Morisky scale, referred as MAQ from here on in this article). While the SGRQ was filled by the patients themselves, the MAQ was filled by the

### Exclusion Criteria

- Patients with history of Cardiac Failure.
- Patients whose breathing might have been affected due to presence of any respiratory or other condition.
- Pregnant females or females who become pregnant during the time of study.
- Patients with terminal illness.
- Severely morbid patients unable to speak or on ventilator support.
- Unconscious or disoriented patients.
- Patients with known learning disabilities.

### Sample Size and Sampling Strategy

The minimum clinically important difference (MCID) is considered to be a four point reduction in the total SGRQ score.<sup>7</sup> For a two sided  $\alpha$  of 0.05, a sample size of 167 patients per group would have 80% power to detect an effect size of 0.3, where effect size is defined as the difference between the means of two groups divided by Standard Deviation (SD).

Patients were randomly assigned to either the 'intervention group' or to the 'usual care group'. Randomization was carried out using the permuted-block randomization method with a block size of four. Because of the nature of intervention, blinding of the patients or the investigators to the intervention was not possible. Although, the data analysts were blinded.

(LAR) of the patient. This was done to avoid introduction of any potential bias by the investigator.

The Case Report Forms (CRFs) were filled by the investigators. CRFs were designed to collect information on patients' demographics, allergies, medication, medication regimen, marital status, economic conditions, occupational status, smoking habits and other addictions, unplanned visits to a clinic or hospital and co-morbidities. To collect these data, patients' medication charts and computerized hospital records were used in conjunction with patient interviews.

Wherever applicable, the investigators then assessed the patient's ability to correctly use an inhalational device(s) prescribed to him/her using the Inhaler Technique Assessment Form. Whenever feasible, patients were subjected to a Pulmonary Function Test (PFT) using MIR SPIROLAB III<sup>®</sup>. At the time of baseline visit, only those patients that belonged to the intervention group received counselling while patients in the usual care group were not counselled at this stage.

#### ***Follow up Visit***

Patients were informed to come for a follow up visit scheduled thirty days from their baseline visit. At the time of follow up visit, patients were re-administered the SGRQ and the MAQ. A CRF was filled again by the investigators. Wherever applicable, patient's ability to correctly use inhalational device(s) were reassessed. Whenever feasible, patients were re-subjected to PFTs and PEF was measured.

On follow up visit, all patients, whether belonging to intervention group or to usual care group, were counselled.

#### ***Study Questionnaires***

Patient Reported Outcomes (PRO) have been found very useful to estimate HRQoL and medication adherence, especially in case of people with COPD and Asthma as this population is heterogeneous in terms of clinical presentation, disease severity and rate of disease progression which makes it difficult to decide what can be construed as a desirable response to the healthcare intervention in question.<sup>[8]</sup> Following instruments were used in this study.

#### **The St George's Respiratory Questionnaire (SGRQ)**

The SGRQ is a standardized self-completed questionnaire for measuring impaired health and quality of life in airways disease. It allows comparative measurements of health between patient populations and quantifies changes in health following therapy.<sup>[9]</sup> It is a 50-item survey forms and calculates scores for three components: symptoms, activity and impact. Scores of these three components are used to calculate a total score which ranges from 0 to 100. The higher the score, poorer is the level of health. A change of four units in the total score is considered as minimum clinically important

difference (MCID). The SGRQ App was used to calculate the scores.<sup>[10]</sup>

#### **Medication Adherence Questionnaire (MAQ)**

The MAQ measures adherence using a four item instrument. Each question has two possible responses: yes or no. Each 'yes' response is scored 0 and each 'no' response is scored 1. Total score can therefore range from 0-4. Based on scores, adherence can be classified as High (a score of 4), Medium (a score of 2 or 3) and Low (a score of 0 or 1). This scale has good validity with Cronbach alpha 0.61.<sup>[11]</sup>

#### ***Inhaler Technique Assessment***

Inhaler technique assessment form was developed after referring to guidelines and protocols laid down by WHO for Pharmacy Based Asthma Services. Same form could be used for either MDI or Rotahaler. There were 11 steps for each inhaler. Each correctly performed step would earn 1 point. Steps number 1, 10 and 11 were not included in the scoring. Step 4 was not included for MDI and step 2 was not included for Rotahaler. Hence, the scores ranged from 0-7 points for each inhaler.<sup>[12]</sup>

#### ***The Process of Counselling***

Counselling was provided to patients by the investigators. Patients were counselled individually by the investigators about their medications and dosage regimen. The counselling sessions were short and no longer than 20 minutes in duration. Counselling sessions included information on the following.

#### **Medication Use and Directions**

They were informed about the medications that were prescribed to them. They were explained the need of each medicine prescribed to them in simple terms. They were made to understand how the medicines were intended to be used and the directions to administer those medicines were explained to them step by step. During the counselling session, investigators made sure that the patient knew the names of medicines prescribed, when to use them, how to use them and for how long are they to be used. Patients were informed about importance of adhering to their prescribed medication regimen.

#### **Inhaler Use**

Whenever an inhaler was prescribed, proper way to use inhalers was taught to the patients. Patients were then asked to repeat the steps to make sure they had properly understood the technique. Steps to use inhalers were reinforced by showing patients YouTube videos.<sup>[13]</sup>

#### **Breathing Exercises**

Simple respiratory exercises have been proved to be very beneficial in patients with COPD and Asthma and hence these were taught to patients.<sup>[14-16]</sup> These included diaphragmatic breathing<sup>[17,18]</sup> and pursed lip breathing.<sup>[19]</sup> Patients were also taught to perform pranayama using four easy techniques – suryabhedna, nadishuddhi, bhramari and kapalbharti.<sup>[20,21]</sup> All these exercises were

demonstrated by the investigators to the patients and then the patients were asked to perform them to ensure that patients had understood how to perform these exercises.

### Diet

Diet and nutritional counselling was given to patients on individual basis and was tailored specifically to their needs. Focus was on increasing nutrient intake, minimizing weight loss and encouraging weight gain. Patients were informed about foods that were rich in omega-3-fatty acids, antioxidants, flavonoids and vitamins C, D and E. It was stressed to patients that high intake of fruits, vegetables and fish would be beneficial and that fast foods were to be avoided.<sup>[22,23]</sup>

### Precautionary Measures

Patients were counselled about various precautions which they could take in order to avoid exacerbations. Patients were informed about following precautions:

- Wearing face masks to avoid dust, pollen or inhalation of other triggers
- Washing hands properly and frequently to prevent infections
- Keeping airways clear of mucous
- Avoiding crowds and congested places
- Keeping inhalers clean

### Smoking Cessation

Patients who still smoked were motivated to stop smoking during counselling session. All patients who were then current smokers were given information about available smoking cessation programs and helplines.<sup>[24,25]</sup>

### Self-Management of Exacerbations

Self-management programs have shown reduction in exacerbations that need hospitalization.<sup>[26]</sup> Patients were given step by step instructions on managing acute exacerbations at home.

### Data Analysis

All data were subjected to Intention-to-Treat (ITT) analysis. All tests of significance were two-sided. For SGRQ scores and subscales, Student's t-test was used and 95% CI was assumed. For MAQ, Chi-Square Test for Association was used. For all tests P-value < 0.05 was considered statistically significant.

Missing data was handled using Last Observation Carried Forward (LOCF) imputation approach.<sup>[27]</sup> Using this approach, the baseline values were carried forward as follow up values for those patients whose follow up data was missing as they did not come for follow up.

## RESULTS

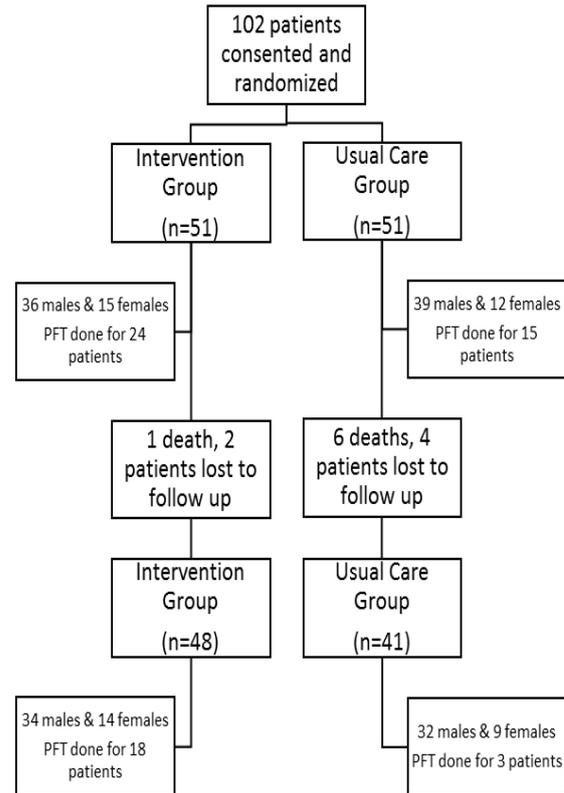


Figure. 2: Study profile.

A total of 102 patients were enrolled into the study, 51 patients in the usual care group and 51 patients in the intervention group. During the study period, a total of 7 patients died of which 6 patients belonged to the usual care group and 1 patient belonged to the intervention group. 2 patients from the intervention group and 4 patients from the usual care group did not come for follow up visit and hence a total of 13 patients were lost to follow up.

Baseline characteristics of both groups were similar in terms of demographic, social, clinical and functional variables. Most of the patients in the study were elderly. There was no significant difference in the SGRQ score during the baseline assessment.

### Unplanned Visits and Deaths

Eleven patients from the intervention group and ten patients from the usual care group had unplanned visits to a local clinic or to the Government Hospital, Aurangabad. One patient from the intervention group died and six patients from the usual care group died during the study period.

### Health Related Quality of Life

HRQoL was measured in terms of SGRQ. At the time of baseline assessment, there was no significant difference in the total SGRQ scores between the usual care group and the intervention group ( $P > 0.05$ ). Also, there were no significant differences in the Symptoms, Activity and Impacts subscales of the SGRQ score between both groups at baseline assessment.

At the time of follow up assessment, after a period of 1 month, the differences between both groups in terms of Symptoms (P = 0.003), Activity (P = 0.038) and Impacts (P = 0.002) subscale and total SGRQ score (P = 0.002)

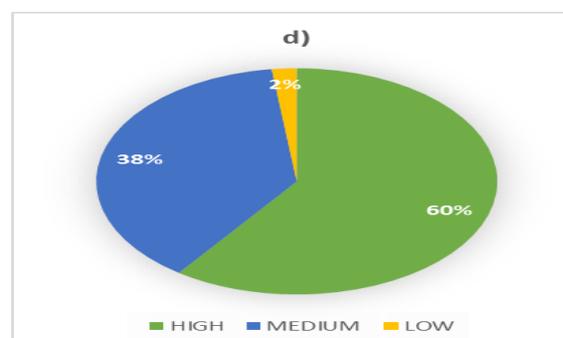
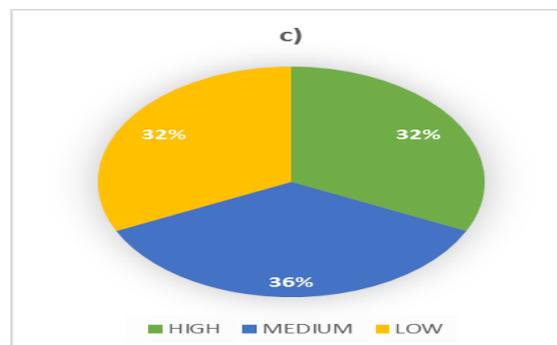
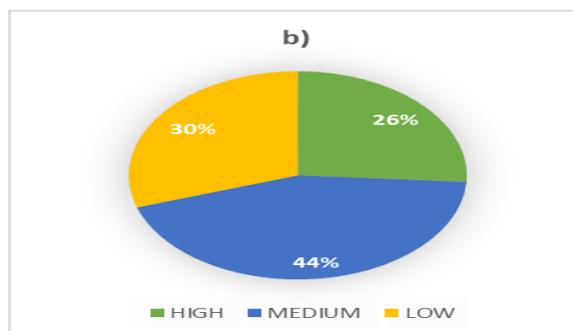
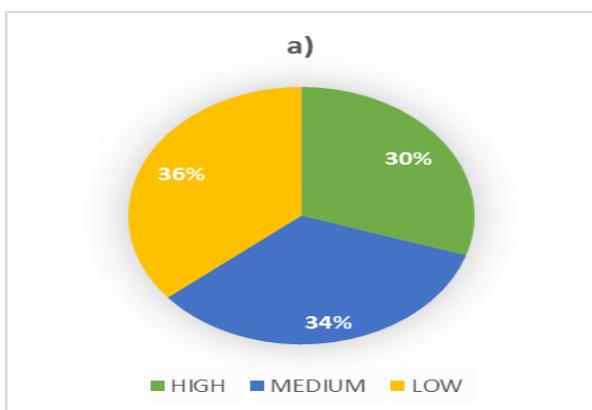
reached a clinical significance (> 4 units) as well as statistical significance (P-value < 0.05). The lowest improvement was seen in the Activity subscale.

**Table. 1: SGRQ scores at baseline and follow up visits.**

SGRQ Scores	Usual Care Group Mean (95% CI)	Intervention Group Mean (95% CI)	Unit Differences (95% CI)	P-value*
<i>Baseline visit</i>				
<b>Symptoms Score</b>	60.81 (55.26,66.35)	57.66 (52.90,62.41)	-3.15 (-10.37,4.07)	0.389
<b>Activity Score</b>	80.66 (75.78,85.54)	83.07 (78.82,87.33)	2.42 (-3.98,8.82)	0.456
<b>Impacts Score</b>	61.94 (57.72,66.17)	58.63 (54.31,62.95)	-3.31 (-9.28,2.66)	0.274
<b>Total Score</b>	67.26 (63.57,70.95)	66.16 (62.60,69.72)	-1.10 (-6.16,3.96)	0.667
<i>1 month Follow up</i>				
<b>Symptoms Score</b>	53.98 (47.81,60.16)	41.40 (36.09,46.71)	-12.59 (-20.63,-4.54)	0.003
<b>Activity Score</b>	76.55 (70.73,82.36)	68.73 (64.03,73.42)	-7.82 (-15.21,-0.43)	0.038
<b>Impacts Score</b>	60.22 (55.25,65.19)	47.33 (40.81,53.86)	-12.89 (-20.99,-4.78)	0.002
<b>Total Score</b>	<b>64.36 (59.63,69.09)</b>	<b>52.91 (47.58,58.24)</b>	<b>-11.44 (-18.48,-4.4)</b>	<b>0.002</b>

**Medication Adherence**

Medication Adherence was measured using the MAQ. At the time of baseline assessment, proportion of patients with high, medium and low adherence were approximately same in both groups. The usual care group had 36%, 34% and 30% patients with low, medium and high medication adherence respectively. Whereas the intervention group had 30%, 44% and 26% patients with low, medium and high medication adherence respectively. But, at 1 month follow up assessment, higher proportion of patients in the intervention group showed high adherence as compared to the usual care group. In the usual care group the proportion of patients with medium adherence rose from 34% to 36% and that of high adherence rose from 30% to 32%. On the contrary, in the intervention group, the proportion of patients with medium adherence changed from 44% to 38% and a huge rise in proportion of patients with high adherence was seen. Proportion of patients with high adherence rose from 26% to 60%, leaving only 2% of the patients with low adherence.

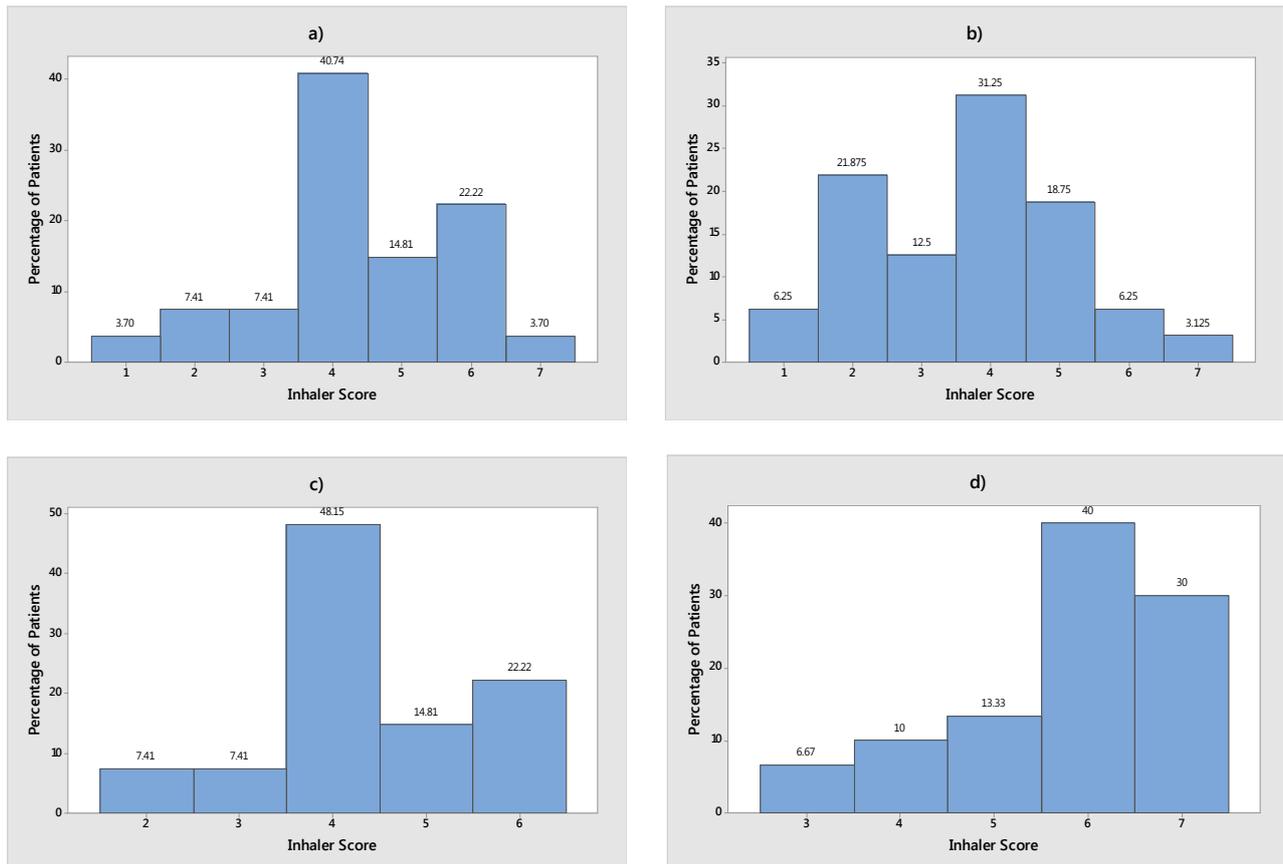


**Figure. 3: Medication Adherence (As Percentage of Subjects In A Study Group) – A) Usual Care Group At Baseline Visit B) Intervention Group At Baseline Visit C) Usual Care Group At 1 Month Follow Up D) Intervention Group At 1 Month Follow Up.**

Chi-Square test for association showed that at the time of baseline assessment, proportions of patients with high, medium and low adherence were not significantly different in the usual care group and intervention group ( $P = 0.348$ ).

But, at 1 month follow up assessment, increase in high level of adherence and decrease in low levels of adherence were significantly associated with the intervention group ( $P < 0.001$ ).

**Inhaler Technique Assessment:** Major proportion of the patients in both the groups had scores 4 or 5 at the baseline assessment. At 1 month follow up assessment, majority of patients belonging to the usual care group still had a score of 4. In fact, it was seen that patients had a tendency to forget few steps of using the inhaler correctly which led to a decrease in the score. In contrast to this, the overall scores of patients belonging to the intervention group had increased drastically at 1 month follow up assessment. Majority of the patients now had a score of 6 or 7 and no patient had a score below 3.



**Figure. 4: Inhaler Technique Assessment Scores – A) Usual Care Group At Baseline Visit B) Intervention Group At Baseline Visit C) Usual Care Group At 1 Month Follow Up D) Intervention Group At 1 Month Follow Up.**

**Pulmonary Function Test:** FEV<sub>1</sub> and FEV<sub>1</sub>:FVC were recorded at baseline visit and at 1 month follow up visit for both groups. For most patients in both groups the results of their PFT at baseline visit were very similar to the results of their PFT at follow up visit, i.e. the change in PFT values for almost all patients who were subjected to PFT was negligible over a period of one month.

## DISCUSSION

All data collection instruments including all the questionnaires and the CRF presented with no difficulties during this study. The reception of counselling by the patients was progressive and optimistic in kind. Overall perception of the patients was that counselling was beneficial and helped them understand and manage their symptoms better. Patients experienced a positive shift in their perception towards their medicines and importance

of adherence to their treatment regimen. Analysis of the data showed a trend of improved outcomes for patients in the intervention group as compared to the patients in the usual care group over a period of 1 month. This study shows an 11 point difference in the total SGRQ scores between the intervention group and the usual care group. A difference this large may be due to many of the following reasons. This study followed an ITT analysis. Next, this study had a short follow up period of one month. This may have resulted in patients still remembering the instructions given to them during the counselling session as the tendency to forget instructions over a period of one month would be quite less as compared to that over three to six months.

### Unplanned Visits and Deaths

Although comparatively more deaths occurred in the usual care group as compared to intervention group, it cannot be said that the given intervention was completely responsible for reduction in mortality. Studies specifically designed for such objective may be necessary to obtain any conclusive information. Also, not much difference was seen in the number of unplanned visits in both groups. This may be due to a short follow up period. Studies with longer follow up periods have demonstrated reduction in unplanned visits following patient education interventions.

### Health Related Quality of Life (SGRQ)

Symptoms related to Asthma and COPD affect a patient's ability to perform activities of daily living to a greater extent, therefore affecting their quality of life.<sup>[28]</sup> Patients demonstrated low HRQoL at baseline assessment, but the HRQoL improved over a period of one month in patients belonging to intervention group as compared to the usual care group. This improvement was clinically and statistically significant. Statistically and clinically significant improvements were also seen in terms of all three subscales of the SGRQ sub-scales viz. the Symptoms scale, the Activity scale and the Impacts scale. In a study carried out by Khmour *et al.*<sup>[29]</sup> it was suggested that intensive approaches are warranted for better outcomes. The results of our study appear to be in agreement with their deduction and further suggest that counselling sessions as short as 20 minutes in duration along with follow up visits timed at a duration of one month may be advantageous, effective and highly beneficial.

### Medication Adherence

Adherence to medications tend to decline over longer time periods with chronic use of medicines, and is inversely related to the number of medications taken by the patient. Since COPD and asthma patients require lifelong therapy, adherence is a larger problem for them.<sup>[30]</sup> Counselling provided to patients in this study had a huge impact on them as the adherence to medications greatly increased in patients belonging to the intervention group as compared to the usual care group. Initially both groups had comparable proportions of patients with low adherence, 36% in usual care group and 30% in intervention group. After counselling, this proportion of the intervention group was reduced from 30% to a mere 2%, whereas 32% of the patients in usual care group still had low adherence. This testifies that counselling can be instrumental in improving patients' medication taking behaviour and therefore improve their overall health.

**Inhaler Use Technique:** Inhalers are a necessary part of patients' medications. They have proved to be tricky to use and many patients have found difficulties using inhalers. Improper use of inhaler may lead to reduced dose delivery or even failure to deliver dose, further leading to sub therapeutic levels of drug in the body and eventually therapeutic failure. Results of the study indicate that counselling serves the purpose of teaching patients the correct way to use inhalers.

### Pulmonary Function Test

Pulmonary Function Test showed negligible changes after 1 month follow up in both groups. These results were not surprising as the parameters FEV<sub>1</sub> and FEV<sub>1</sub>:FVC were not expected to be sensitive to the intervention given to the patients. Similar studies have also reported negligible changes in the Pulmonary Function Test.

### Unique Features of this Study

- This study was meticulously designed for Indian Healthcare settings.
- The intervention included only counselling the patients and no attempts were made to modify the prescribed treatment.
- Counselling sessions were as short as 20 minutes. Short counselling sessions were conducted in this study to facilitate an extremely important task of handling huge number of patients in the Indian Healthcare settings.
- This study considers that number of patients lost to follow up is dependent on the intervention and therefore this study uses an Intention-To-Treat Analysis which includes the patients who were lost to follow up.

### Limitations

- This study had a short follow up period of 1 month.
- This study was not designed to evaluate whether the effectiveness of the given intervention decreased with longer duration or not.
- The target sample size was not met for this study. Coincidentally, the sample size achieved was sufficient to detect a difference of 8 points or more in total SGRQ scores at  $\alpha = 0.05$  and power = 80%

### CONCLUSION

This study was designed with the objective to measure the impact of short counselling sessions on the HRQoL in patients with Asthma and COPD, along with changes in other outcomes like medication adherence, ability to correctly use inhalers and number of unplanned hospital visits or hospitalisations. The results revealed that the outcomes in intervention patients improved overall when compared with that of the usual care patients. Short counselling sessions at short intervals of 1 month have proven to be very efficient. Such sessions conducted regularly at such short intervals might be considered as an intensive approach in reinforcing treatment intended by the physician. This study was small and single-centred and designed typically for the needs of Indian healthcare system. Further studies are needed to

investigate how frequently such interventions are needed in order to maintain similar effectiveness.

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